UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/093,972	06/09/98	NYCE J	P6641031

EXAMINER

HM22/0326

VIVIANA AMZEL, PH.D.
EPIGENESIS PHARMACEUTICALS, INC.
7 CLARKE DRIVE
CRANBURY NJ 05812

ART UNIT	PAPER NUMBER
1635	22

DATE MAILED: 03/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

*U S GPO 2000-473-000/44602

Advisory Action	Application No. 09/093,972	Applicant(s) NYCE, JONATHAN W.	
	Examiner Janet L Epps	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 February 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search. (see NOTE below);

   (b) ☐ they raise the issue of new matter. (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see attached action*.

4. ☐ Applicant's reply has overcome the following rejection(s): _____.

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

6. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: *108-124,126-130,133-175,178-181,183-190,192-198,200-218 and 221-228*.

   Claim(s) objected to: _____.

   Claim(s) rejected: *125, 131, 191, 219-220, 229-231*.

   Claim(s) withdrawn from consideration: _____.

9. ☐ The proposed drawing correction filed on _____ a)☐has b)☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

11. ☒ Other: *see attached action.*

DETAILED ACTION

***NOTE: A draft copy of this office action was faxed to Applicant's representative on 3-21-01. The instant office action differs from the original draft copy.

Substitute Specification

1. As stated in the Official Action mailed 11-07-00, the Substitute specification filed 5-11-00 does not comply with 37 CFR 1.125. See MPEP § 608.01(q) and §714.20. Specifically, the Substitute specification was not accompanied by a statement that the substitute specification includes no new matter.

Response to Amendment

2. The amendment to the specification filed 5-11-00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows:

Applicants have amended the specification by claiming priority to multiple copending applications and have added material directly from these applications into the body of the specification. However, Applicant's amendments are improper since the specification as originally filed failed to provide a statement to incorporate the entirety of the disclosures of the previously filed applications to which a priority is now being claimed.

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the

purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. See MPEP § 608.01(p).

Specifically, Applicants have amended the specification to recite that "[t]he present invention may be used to treat airway disease in a subject for any reason..", however the original specification only supports treatment of airway diseases and conditions that are mediated by adenosine receptors. Applicants have added targets (see Example 6 of substitute specification) and exemplary oligonucleotides, specifically SEQ ID NO: 997-1035, that were originally disclosed in Applications 08/474,497 and 09/016,464.

Applicant is required to cancel the new matter in the reply to this Office action.

3. Applicants have included an un-numbered claim after claim 125, in the amendment filed 2-07-01. It is unclear if Applicants intended for this claim to be deleted or examined. Additionally, there are two claims numbered 131, there are no claims numbered 132, 182, or 199. Moreover, there are no claims numbered 176 or 177, the numbering skips from 175 to 178.

Sequence Listing

4. As stated in the Official Action mailed 11-07-2000, the Declaration submitted under 37 CFR 1.821(f) is unacceptable, Applicant's representative stated that the paper

and computer readable copies of the sequence listing submitted in accordance with 37 CFR 1.821(c) and 1.821(e), "include no new matter and are, to the best of the applicant's knowledge, the same as the sequence submitted with the application as filed, except for sequence 997-1035, which sequences have been added to the application supported by the disclosure of the parent application USSN 08/474,497." This statement is unacceptable, as indicated above the original specification as filed does not incorporate the disclosure of 08/474,497 in its entirety. Applicants were requested to provide a statement that the content of the paper and computer readable copies are the same, and where applicable, include no new matter, as required by 37 CFR 1.821(e)-(g) or 1.825(b) or 1.825(d).

5. The reply filed 5/11/00 is not fully responsive to the communication mailed 01/04/00 for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 168 and 231 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 168 recites "anti-vial", the metes and bounds of this term are unclear. It is likely that applicants intended this claim to recite "anti-viral."

Claim 231 recites the limitation "kiy" of claim 164, there is lack of antecedent basis for this limitation in the claim. It is likely that applicants intended this claim to recite "kit."

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 125, 131, 191, 219-220, 229-231 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claims 125, 131, 219, 231 to recite oligo(s) comprising a sequence selected from SEQ ID NO: 1, 3, 5, or 7 to 1035. However, the instant claims recite elements without support in the original disclosure, particularly SEQ ID NO: 997-1035.

Claims 131, 191, and 220 were amended to recite surfactants not discussed in the original specification, specifically colfoceryl-cetylalcohol-tyloxapol, colfosceril palmitate, cetylalcohol and neutral lipids. The specification should provide clear support or antecedent basis for all terms used in the claims.

Claims 229-230 recite gene targets for the design of antisense oligonucleotides that were not described in the specification as originally filed.

Allowable Subject Matter

10. Claims 108-124, 126-130, 133-167, 168-175, 178-181, 183-190, 192-198, 200-218, 221-228 are allowable over the prior art or any combination thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

jle
March 23, 2001

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600